

Acurx Pharmaceuticals, Inc. Reports Fourth Quarter and Full Year 2021 Results and Provides Business Update

STATEN ISLAND, N.Y., March 17, 2022 /PRNewswire/ -- Acurx Pharmaceuticals, Inc. (NASDAQ: ACXP) ("Acurx" or the "Company"), a clinical stage biopharmaceutical company developing a new class of antibiotics for difficult-to-treat bacterial infections, announced today certain financial and operational results for the fourth quarter and full year ended December 31, 2021.

Highlights of the fourth quarter and full year ended December 31, 2021 include:

- Acurx is currently enrolling patients in a Phase 2b clinical trial, which will include up to 16 U.S. sites, in patients with *C. difficile* infection (CDI) with enrollment expected to be completed in the second half of 2022;
- The Phase 2b clinical trial will compare the efficacy of oral ibezapolstat, the Company's lead antibiotic candidate, to oral vancomycin, the current standard of care for CDI.
- Additional microbiome data from the Phase 2a trial of ibezapolstat in patients with CDI were presented at three prominent scientific conferences throughout 2021;
- Through its collaboration with University of Houston, the Company commenced a laboratory study of ibezapolstat to build upon the favorable microbiome data from the Company's Phase 1 and Phase 2a clinical trials. This new study will compare the impact of ibezapolstat on the microbiome as compared with other commonly used antibiotics to treat patients with CDI, namely, fidaxomicin, vancomycin, and metronidazole and the Company anticipates completing this study in the second half of 2022;
- The Phase 2a trial demonstrated 100% clinical cure and 100% sustained clinical cure with ibezapolstat along with beneficial microbiome changes during treatment including overgrowth of Actinobacteria and Firmicutes phylum species while on therapy and new findings which demonstrate potentially beneficial effects on bile acid metabolism;
- These reported clinical results support the expectation that microbiome effects may be predictive of beneficial patient outcomes including low rates of recurrence;
- The previously announced R&D program in collaboration with Leiden University Medical Center in Holland is ongoing to further evaluate the mechanism-of-action of Acurx's inhibitors against the DNA pol III C enzyme, which is the bacterial target of the Company's antibiotic product pipeline.

Fourth Quarter and Full Year 2021 Financial Results

Research and development expenses for the year ended December 31, 2021 were \$2.0 million compared to \$2.2 million for the year ended December 31, 2020. The decrease is due to lower consulting expenses partially offset by higher manufacturing costs associated with the commencement of the Phase 2b trial. For the three months ended December 31, 2021, research and development expenses were \$0.7 million compared to \$0.5 million for

the three months ended December 31, 2020. The increase is due to Phase 2b trial related costs which commenced in the fourth quarter.

General and administrative expenses for the year ended December 31, 2021 were \$10.8 million compared to \$2.4 million for the year ended December 31, 2020. The increase was primarily due to non-cash stock-based compensation, as well as an increase in professional fees, insurance and legal costs.

For the three months ended December 31, 2021, general and administrative expenses were \$1.9 million compared to \$0.6 million for the three months ended December 31, 2020. The increase in general and administrative expenses is primarily attributable to increases in employee compensation costs, as well as an increase in professional fees, insurance and legal costs.

Conference Call

As previously announced, David P. Luci, President and Chief Executive Officer, and Robert G. Shawah, Chief Financial Officer, will host a conference call to discuss the results and provide a business update as follows:

Date:	Thursday, March 17, 2022
Time:	8:30 a.m. ET
Toll free (U.S. and International):	877-790-1503
Conference ID:	13727463

About Ibezapolstat

Ibezapolstat is a novel, orally administered antibiotic being developed as a Gram-Positive Selective Spectrum (GPSS™) antibacterial. It is the first of a new class of DNA polymerase III C inhibitors under development by Acurx to treat bacterial infections. Ibezapolstat's unique spectrum of activity, which includes *C. difficile* but spares other Firmicutes and the important Actinobacteria phyla, appears to contribute to the maintenance of a healthy gut microbiome.

In June 2018, ibezapolstat was designated by the U.S. Food and Drug Administration (FDA) as a Qualified Infectious Disease Product (QIDP) for the treatment of patients with CDI and will be eligible to benefit from the incentives for the development of new antibiotics established under the Generating New Antibiotic Incentives Now Act. In January 2019, FDA granted "Fast Track" designation to ibezapolstat for the treatment of patients with CDI.

The Company successfully completed Phase 1 and Phase 2a clinical trials of ibezapolstat and it is currently enrolling patients in its Phase 2b vancomycin-controlled efficacy study in a 1:1 randomized trial of a total of 64 patients with CDI.

The CDC has designated *C. difficile* as an urgent threat highlighting the need for new antibiotics to treat CDI.

About Acurx Pharmaceuticals, Inc.

Acurx Pharmaceuticals is a clinical stage biopharmaceutical company focused on developing new antibiotics for difficult to treat infections. The Company's approach is to develop antibiotic candidates that target the DNA polymerase III C enzyme and its R&D pipeline includes antibiotic product candidates that target Gram-positive bacteria, including

Clostridioides difficile, methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin resistant Enterococcus (VRE) and drug-resistant *Streptococcus pneumoniae* (DRSP).

To learn more about Acurx Pharmaceuticals and its product pipeline, please visit www.acurxpharma.com.

Forward-Looking Statements

Any statements in this press release about our future expectations, plans and prospects, including statements regarding our strategy, future operations, prospects, plans and objectives, and other statements containing the words "believes," "anticipates," "plans," "expects," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: whether ibezapolstat will benefit from the QIDP designation; whether ibezapolstat will advance through the clinical trial process on a timely basis; whether the results of the clinical trials of ibezapolstat will warrant the submission of applications for marketing approval, and if so, whether ibezapolstat will receive approval from the FDA or equivalent foreign regulatory agencies where approval is sought; whether, if ibezapolstat obtains approval, it will be successfully distributed and marketed; and other risks and uncertainties described in the Company's annual report filed with the Securities and Exchange Commission on Form 10-K for the year ended December 31, 2021, and in the Company's subsequent filings with the Securities and Exchange Commission. Such forward-looking statements speak only as of the date of this press release, and Acurx disclaims any intent or obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements, except as may be required by law.

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FINANCIAL TABLES FOLLOW

ACURX PHARMACEUTICALS, INC.
BALANCE SHEETS
AS OF DECEMBER 31, 2021 and 2020

	December 31, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS		
Cash	\$ 12,958,846	\$ 3,175,411
Prepaid Expenses	<u>295,304</u>	<u>48,609</u>
TOTAL ASSETS	<u>\$ 13,254,150</u>	<u>\$ 3,224,020</u>
LIABILITIES AND SHAREHOLDERS' AND MEMBERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable and Accrued Expenses	\$ 843,909	\$ 455,931
Paycheck Protection Program Loan	-	<u>16,625</u>
TOTAL CURRENT LIABILITIES	843,909	472,556
NONCURRENT LIABILITIES		
Paycheck Protection Program Loan	-	<u>49,878</u>
TOTAL LIABILITIES	<u>843,909</u>	<u>522,434</u>
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' AND MEMBERS' EQUITY		
Members' Equity, Class A	-	16,402,198
Members' Equity, Class B	-	100,000
Common Stock; \$.001 par value, 200,000,000 shares authorized, 10,215,792 shares issued and outstanding at December 31, 2021	10,216	-
Additional Paid-In Capital	38,948,334	-
Accumulated Deficit	<u>(26,548,309)</u>	<u>(13,800,612)</u>
TOTAL SHAREHOLDERS' AND MEMBERS' EQUITY	<u>12,410,241</u>	<u>2,701,586</u>
TOTAL LIABILITIES AND SHAREHOLDERS' AND MEMBERS' EQUITY	<u>\$ 13,254,150</u>	<u>\$ 3,224,020</u>

ACURX PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2021 AND 2020

	2021	2020
OPERATING EXPENSES		
Research and Development	\$ 2,030,177	\$ 2,202,979
General and Administrative	<u>10,784,023</u>	<u>2,397,059</u>
TOTAL OPERATING EXPENSES	12,814,200	4,600,038
Gain on Forgiveness of Paycheck Protection Program Loan	<u>66,503</u>	-
NET LOSS	<u>\$ (12,747,697)</u>	<u>\$ (4,600,038)</u>
LOSS PER SHARE		
Basic and diluted net loss per common share/units	<u>\$ (1.49)</u>	<u>\$ (0.74)</u>
Weighted average common shares/units outstanding basic and diluted	<u>8,535,873</u>	<u>6,190,875</u>

View original content:<https://www.prnewswire.com/news-releases/acurx-pharmaceuticals-inc-reports-fourth-quarter-and-full-year-2021-results-and-provides-business-update-301503861.html>

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